PB85-102705

Guidance for the Reregistration of Pesticide Products Containing Thiram as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Prepared for

29 Jun 84

U.S. Department of Commerce
National Technical Information Service
NTIS

PB85-102705

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

THIRAM
AS THE ACTIVE INGREDIENT

EPA CASE NUMBER 22

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE AND TOXIC SUBSTANCES
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

Washington, DC 20460

June 29, 1984

EPA-540/RS-84-006

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

3. Recipient's Accession No. PB85 102705

4. Title and Subtitle

Guidance for the Reregistration of Pesticide
Products Containing Thiram as the
Active Ingredient.

5. Report Date 6/84

6.

7. Author(s) USEPA, Office of Pesticide Programs, Registration Division

8. Performing Organization Rept. No. EPA-540/RS-84-006

9. Performing Organization Name and Address

Environmental Protection Agency
Office of Pesticide Programs
401 M. St. SW
Washington, DC 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.

(C)

(G)

12. Sponsoring Organization Name and Address

same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement:

19. Security Class (This Report) unclassified

21. No. of Pages 104

20. Security Class (This Page)

22. Price

(See ANSI–Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4–77)
(Formerly NTIS–35)
Department of Commerce

TABLE OF CONTENTS

Introduction 1

I. Regulatory Position and Rationale. 4

II. Requirement for Submission of Generic Data 20

III. Requirement for Submission of Product-Specific Data 46

IV. Submission of Revised Labeling and Packaging Information. 50

- A. Label Contents 50
  - 1. Product Name 50
  - 2. Company Name and Address 50
  - 3. Net Contents 50
  - 4. Product Registration Number. 51
  - 5. Producing Establishment Registration Number. 51
  - 6A Ingredient Statement 51
  - 6B Pounds Per Gallon Statement. 51
  - 7. Front Panel Precautionary Statements 51
  - 7A Child Hazard Warning Statements. 52
  - 7B Signal Word. 52
  - 7C Skull and Crossbones and Word Poison 52
  - 7D Statement of Practical Treatment 52
  - 7E Referral Statement 52
  - 8. Side/Back Panel Precautionary Labeling 52
  - 8A Hazard to Humans and Domestic Animals. 53
  - 8B Environmental Hazard 53
  - 8C Physical or Chemical Hazard. 53
  - 9 Misuse Statement 54
  - 10A Storage and Disposal Block 54
  - 10B Directions for Use 54

54

- B. Collateral Information 54

V. Instructions for Submission. 55

APPENDICES

		Page
II-1	Bibliography (Including Guide for Use)	56
II-2	FIFRA §3(c)(2)(B) Summary Sheet - EPA Form 8580-1	67
II-3	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data EPA Form 8580-6	68
III-1	Product Specific Data Report	69
IV-1	Labeling Requirements and Use Classificataion (40 CFR §162.10 and 40 CFR §162.11)....................	70
IV-2	Table of Labeling Requirements and Sample Labels	75
IV-3	Physical/Chemical Hazards Labeling Statement	79
IV-4	Storage and Disposal Instructions	80

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g)) directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient must apply for reregistration.

To fulfill this congressional mandate, EPA has established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its use. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active inredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or their source does not take necessary steps to comply with the data production requirements. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, in compliance with the data production requirements, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time frames outlined. EPA will issue a notice of intent to cancel or suspend the registrations of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Adminstrator, EPA was enjoined from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA has appealed this decision to the U.S. Supreme Court. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This Registration Standard describes the regulatory position of the Environmental Protection Agency (EPA) on bis(dimethylthiocarbamoyl)disulfide (thiram), based on an evaluation of all registered manufacturing-use products (MUP's), formulation-use products (FUP's), and certain end-use products containing thiram as the sole ingredient. Labeling requirements, tolerances, special local needs registrations authorized by Section 24c of the FIFRA, as well as registrations under Section 3 of FIFRA were considered in this analysis. The Agency sets forth the data requirements that must be met to register or reregister products covered by this Standard.

This Standard addresses registration requirements for current and future MPs. Thiram MPs that differ appreciably from those described here may require amendments to this Standard. Also, use-patterns that differ from those described here may also require amendments to this Standard.

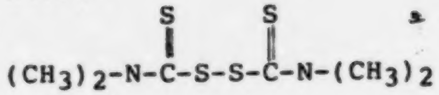
B. USE PROFILE

Thiram is the acceptable common name for bis (dimethylthiocarbamoyl)disulfide and is recognized by the American National Standards Institute. Trade names and other names for thiram are AAtak, Arasan, Delsan, Mercuram, Nomersan, Polyram-Alltra, Pomarsol, Spatrete, Tersan, Thimer, Thiramad, Thirasan, Thiuramin, Trametan, Triampa, Tripomol, Tuads, Vancide, Tetramithylthiuram disulfide, TM-95, TMTD, and TMTDS.

There are ten (10) "manufacturing-use" and/or "formulation use" thiram products that may be used in the manufacture of another end-use pesticide product which bears labeling that identifies thiram as one of the active ingredients. The percent thiram in these products range from 65 to 99.45. The Office of Pesticide Programs Internal Control Number (EPA Shaughnessy Number) for thiram is 079801-7, and its CAS Number is 137-26-8.

Thiram has the following identifying characteristics:

Empirical Formula: $C_6H_{12}N_2S_4$
Molecular Weight: 240.4
Structural Formula:



$$(CH_3)_2\text{-}N\text{-}\overset{\overset{S}{\|}}{C}\text{-}S\text{-}S\text{-}\overset{\overset{S}{\|}}{C}\text{-}N\text{-}(CH_3)_2$$

Thiram is a broad spectrum fungicide that has registered uses for control of diseases of fruits, vegetables, and ornamentals (including turf) for seed rot and seedling diseases of vegetables and field crops (as a seed treatment), for post-harvest diseases of bananas (as a fruit dip or spray), for diseases of sweet potatoes, tree seedlings, plant cuttings and ornamental bulbs (as a seedling or propagule treatment), to control diseases of onions (as a soil treatment), for mold and mildew control in textiles and polyurethane (as a spray or additive), for slime control in the manufacture of paper, and for repelling animals from various application sites.

Thiram is formulated into dusts, granules, liquid concentrates, pastes, wettable powders and flowable suspenpesnsions. Thiram is also formulated in combination with a variety of insecticides.

The major use of thiram is in rubber processing as an accelerator and vulcanizer. It has also been used as a bacteriostat in soap.

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on thiram, the Agency has made the following determinations:

1. Manufacturing-use pesticide products containing thiram as a sole active ingredient may be registered for sale, distribution, formulation and use in the United States, subject to the terms and conditions specified in this standard. Applicants having products not conforming to this standard must apply to amend the document so those products containing thiram may be registered and reregistered. Mixtures and end-use products containing thiram may not be registered or reregistered under this standard. However, the use patterns of the end-use products were considered for purposes of determining generic data requirements for thiram.

2. Available data do not show that any of the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of thiram specified in this standard.

3. Registrants must provide or agree to develop additional data, as specified in the tables attached to this standard, in order to maintain existing registrations or to permit new thiram registrations.

4. Under this standard precautionary labeling of all products must be revised as stated under Required Labeling. In addition all end-use products intended for crop use, except seed, seed piece and plant propagule treatments must bear labeling restrictions for crop rotation and for reentering treated areas.

5. Limited data are available to identify the movement and fate of thiram in soils. Because this data indicate a potential for ground water contamination, the Agency is requiring data needed to assess this potential (see Table A, Environmental Chemistry Data).

D. REGULATORY RATIONALE

1. Based on historical use experience (human health effects reports) and the benefits from the pesticidal uses, the Agency has determined that it should allow the registration of thiram products to continue for existing use-patterns until the risk of hazards are better defined by the data requirements specified in Table A and B of this document. Regulatory action may be needed when the risk of hazards has been identified.

2. Two worker exposure effects have been identified:

   a. Illness in pine-seedling planters and handlers resulting from handling thiram-treated pine seedlings without protective clothing (the illness results from the ingestion of alcohol after such an exposure).

      Note: Thiram is the methyl analog of Antabuse, bis-(diethylthiocarbomyl sulfide), a drug used in rehabilitating alcoholics.

   b. Skin rashes of the hands and head resulting from exposure to thiram in handling thiram-treated pine seedlings.

These health effects have been reduced by label precautions and will be reduced further by label precautions under this Standard that require workers to wear gloves and protective clothing when handling thiram treated products.

3. As all of the required toxicology data to support the uses of thiram MUP and FUP products have never been submitted or were submitted and are presently considered to be inadequate to support established registrations and tolerances, regulatory actions regarding the tolerances must await the receipt of these data. Section 180.132 of the Code of Federal Regulations, Title 40, Parts 150 to 189 lists the tolerances for thiram.

4. The registered seed treatment uses of thiram have been considered non-food or non-feed uses. A review of the residue chemistry data available indicated that the data were inadequate to support the seed, seed-piece and other plant propagule treatment uses as non-food or non-feed uses. Data requirements to support these uses are listed in Table A and B.

5. The Agency has a concern for ground water contamination because preliminary data indicate that thiram is very mobile in silty clay loam soil and has a half-life of 4 to 5 weeks in neutral soil. Under this Standard, data are required on an accelerated basis to determine this potential risk of hazard.

6. Thiram meets the criteria of 40 CFR, Section 158.140. Therefore an interim 24-hour reentry interval has been applied until the receipt and evaluation of reentry data specified in Table A, Section 158.130, Subpart K, Re-entry.

7. It is not the Agency's policy to cancel or to withhold registration merely because data are missing or inadequate (See Sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, publication of this standard provides a mechanism for identifying data needs and registration under the standard allows for the upgrading of labels during the period in which the required data are being developed. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of thiram products.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

All products that contain thiram as the sole active ingredient are subject to this standard and must either comply with the acute toxicity limits, product composition, and use patterns requirements listed in Section F of this document or submit data and a justification to amend the standard to encompass such products.

The applicant for registration of reregistration of products subject to this standard must comply with all terms and conditions described in it, including committing to fill data gaps on schedule. Applicants for registration under this standard must followthe instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

Technical grade products must contain at least 97.0 percent thiram as the sole active ingredient. Each manufacturing-use product must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the manufacturing-use thiram products must be substantially similar to that in currently registered technical products. Any manufacturing-use product not meeting these requirements will be considered a new product and will require an amendment to the standard.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing thiram for acute toxicity category II, provided that the labeling of those products bear appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing thiram may be labeled for formulation only into end-use products for use as a fungicide for foliar applications to fruits, vegetables and ornamentals (including turf), and as a seed treatment for vegetable and field crops; as a post-harvest treatment of bananas; as a pre-planting dip for sweet potatoes, tree seedlings, cuttings, and ornamental bulbs; as a soil treatment for onions; as a treatment in manufacture of paper, textiles, and polyurethane; and as an animal repellent.

G. REQUIRED LABELING

All technical grade and manufacturing-use products containing thiram must bear appropriate labeling as specified below and in 40 CFR 162.10. Other portions of this guidance package contain specific information regarding labeling requirements.

Precautionary statements to be used on labeling of thiram products:

1. All end-use products with labeling for use on tree seedlings (conifer and deciduous species), plant propagules and any other use site (commodity) that may be directly handled, such that human skin is exposed to the treated commodity, must bear use precautions under the Directions for Use heading that instructs:

"(Name of use site(s), e.g. pine seedlings) that are treated with this product must bear distinct labeling that instructs:

CAUTION: Treated with thiram. Wear rubber gloves and protective clothing when handling products treated with thiram. Direct exposure to skin may result in severe dermatitis."

2. All end-use products that bear labeling for seed treatment must include the following precautionary statements:

   Causes eye and skin irritation. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Avoid inhaling of spray mist or dust. Do not use or store near food or feed.

   During commerical exposure in seed treatment and loading operations, wear goggles, clean rubber gloves, protective clothing, and a pesticide respirator jointly approved by the Mine Safety and Health Administration (formerly the U. S. Bureau of Mines) and by the National Institute of Occupational Safety and Health under provisions of 30 CFR, Part 11. Wash hands, arms and face thoroughly with soap and water after handling and before eating or smoking. Routinely shower or bathe after work, wash all clothing with soap and hot water before reusing.

3. All products, manufacturing-use and end use, must bear the labeling precautionary statement:

   Consumption of alcoholic beverages increases the toxic effects of thiram.

In addition, the following specific environmental hazard labeling requirements apply to technical and manufacturing-use products:

1. All MUPs must bear the following precautionary statements:

   This pesticide is toxic to fish. Do not discharge into lakes, streams, ponds, or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office or the Environmental Protection Agency.

2. All end-use products (EUPs) intended for outdoor use, including seed treatments, must bear the following precautionary statements:

This pesticide product is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of material. Drift or ranoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands.

3. Both MUPs and EUPs may need special labeling to protect endangered species. This will be determined after the required environmental chemistry data are reviewed, and in conjunction with EPA's evaluation of the potential risk of hazards to endangered species.

All end-use products intended for crop use, except seed, seed piece and plant propagule treatments must bear the use restriction:

> Do not rotate treated crop with crops other than those with registered thiram uses.
>
> Do not reenter treated areas within 24-hours following application unless protective clothing is worn.

H. Tolerance Reassessment

1. Non-Seed Applications

The established tolerances for thiram are presently expressed as the fungicide thiram (tetramethyl thiuram disulfide) without specifying any metabolites. The metabolism of thiram in plants and animals is not adequately understood. Available data do not provide direct evidence that thiram is or is not absorbed by root or shoot portions of plants. Therefore, it is not known whether or not thiram is systemic.

Thiram per se has not been identified as a residue in root-treated plants, however it has not been adequately sought. The following metabolites of thiram have been tentatively identified in plant sap using a fungal bioassay on paper chromatographs: DDC-beta-glucoside (DDC= dimethyldithiocarbamate), DDC-L-alanine, thiazolidine-2-thione-4-carboxylic acid, and an unidentified fungitoxic compound. The residues of concern cannot be determined at this time due to the inadequacy of the available data. Also, the nonfood use category for thiram seed treatments cannot be upheld or denied until the receipt of the requested plant metabolism data.

Reassessment of the established thiram tolerances must await receipt and evaluation of the toxicological studies as requested on the accompanying Tables A and B. The available toxicological data are unacceptable for use in establishing tolerances. Consequently, a "No Observable Effect Level" (NOEL) cannot be established at this time, hence a maximum permissible intake (MPI) cannot be calculated.

The following table lists the present status for tolerances in parts per million for residues of thiram:

Raw Agricultural Commodity	U.S.	Canada	Mexico	Codex
Apples	7	0.1	7	3[b]
Bananas	7[a]	1.0	-	1[c]
Celery	7	-	7	5[b]
Onions (dry bulb)	0.5	-	0.5	-
Peaches	7	7	7	3[b]
Strawberries	7	7	7	3[b]
Tomatoes	7	7	7	3[b]

2. Seed Applications:

No tolerances have been established for thiram residues in or on any crop for which thiram is registered solely for seed treatment, because heretofore seed treatment uses have been considered to be nonfood uses. These crops include: barley, beans (dry and succulent), lima beans, beets, broccoli, brussels sprouts, cabbage, cantaloupe, carrots, castor bean, cauliflower, collards, corn (sweet and field), cotton, cowpeas, cucumber, eggplant, endive, flax, forage-fodder grasses, kale, kohlrabi, lentils, lettuce, millet, muskmelons, mustard, oats, okra, onion, peanuts, peppers, pumpkins, radish, rice, rye, safflower, sesame, small-seeded legumes, sorghum, soybeans, spinach, sugar beets, sunflower, swiss chard, tomato, turnips, watermelon, and wheat.

---

a. 7 parts per million in or on bananas (from preharvest and postharvest application) of which not more than 1 part per million shall be in the pulp after peel is removed and discarded.

b. A temporary Codex MRL for the residues of dithiocarbamates (of which thiram is a member) expressed in terms of mg CS_2/kg, has been established.

c. Temporary Codex MRLs of 1 and 0.1 ppm have been established for total dithiocarbamates residues (including thiram expressed as ppm CS_2) in or on whole bananas and banana pulp, respectively.

Use directions and limitations:

The use directions and limitations for seed-treated crops are outlined in the table below.

Crop	Formulations	Treatment rate[a]	Comments
Barley	50-75% D 50% WP/D 2.9-4 lb/gal FlC	2.05(d) 1.16-2.21(s)	
	43-70% WP 3.75-70/5 WP/D 1.67 lb/gal (17%) RTU	0.063-1.935 (mai,s)	
Beans (dry and succulent types)	25-75% D 65-75% WP 50% WP/D 2.9-4 lb/gal FlC 1.22 lb/gal (12.71%) RTU	0.975-1.05 (d,s)	
	75% D 43-70% WP 70% WP/D	0.93-1.075 (mai,s)	
Beans, lima	25-75% D 65-75% WP 50% WP/D 2.9-4 lb/gal FlC	1.5-1.65(d) 1.4-1.575(s)	
	75% D 43-70% WP 70% WP/D	1.4-1.61(mai)	
Beets	50-75% D 75% WP 50% WP/D 3-4 lb/gal FlC	4.0(d) 2.48-4.2(s)	
	75% D 43-70% WP 70% WP/D	4.3(mai,d) 3.73-4.0(mai,s)	
Broccoli Brussels Sprouts Cabbage	50-75% D 75% WP 50% WP/D	4.0(d) 2.48-4.2(s)	

Carrots	3-4 lb/gal FlC		
Cauliflower			
Collards	75% D	3.73-4.0(mai,s)	
Endive	70% WP		
Kale	70% WP/D		
Kohlrabi	(as above)		
Lettuce			
Mustard			
Peppers			
Radish			
Spinach			
Swiss Chard			
Turnips			
Cantaloupe	50-75% D	2.25(d)	
Cucumber	75% WP	1.28-2.36(s)	
Pumpkin	50% WP/D		
Squash	2.9-4 lb/gal FlC		
Watermelons			
	75% D	2.1-2.635(d)	
	43-70% WP	2.1(s)	
	70% WP/D		
Castor Bean	50-75% D	2.25(d)	
	75% WP	2.25-2.36(s)	
	50% WP/D		
	3 lb/gal FlC		
	75% D	2.1-2.25(mai,s)	
	70% WP		
	70% WP/D		
Corn, field	50-75% D	1.5(d)	
	75% WP	1.28-1.575(s)	
	50% WP/D		
	3-4 lb/gal FlC		
	2.9-3.8 lb/gal FIC	0.75-0.95	Unspecified method of treatment
	18.5-75% D	1.12(mai,s)	
	42-70% WP		
	70% WP/D		
Corn, Sweet	50-75% D	1.5-2.67(d)	
	75% WP	2.5-3.98(s)	
	50% WP/D		
	4 lb/gal FlC		
	50% WP/D	1.47-1.52(s)	
	2.9-3.8 lb/gal FlC		

	75% D 42-43% WP 37.5-70% WP	1.5-3.76(mai,s)	
	18.5% D	0.74 oz/bu(mai,s)	
Cotton	50-75% D 75% WP 50% WP/D 3-4 lb/gal FlC	2.25(d) 1.39-2.36(s)	Treatment is different for acid, delinted, reginned or fuzzy seed (see labels for details)
	75% D 43-70% WP 37.5-70% WP	2.1-3.0(mai,s)	
	2.9-3.8 lb/gal FlC	0.86-12	Unspecified method of treatment.
Cowpeas	50-75% D 75% WP 50% WP/D 3-4 lb/gal FlC 1.22 lb/gal (12.71%) RTU 1.24 lb/gal (13.85%) RTU	1.0-1.05(d) 0.975-1.05(s)	
	75% D 43-70% WP 70% WP/D	0.93-1.075(mai,s)	
Eggplant	50-75% D	3.0(d)	
Okra	75% WP 50% WP/D 3-4 lb/gal FlC	1.86-3.15(s)	
	75% D 70% WP 70% WP/D	2.8-4.0(mai,s)	
Flax	50-75% WP 50% WP/D 2.9 lb/gal FlC	2.65(d) 1.41-2.775(s)	
	70% WP 70% WP/D	1.4 oz/bu(mai,s)	
Forage-Fodder			
Grasses	50-75%	4.0(d)	

	75% WP	4.0-4.2(s)	
	50% WP/D		
	3-4 lb/gal FlC		
	75% D	3.73-4.0(mai,s)	
	70% WP		
	70% WP/D		
	3 lb/gal FlC	2.48	Unspecified method of application.
Lentils	3 lb/gal EC	1.54	Unspecified method of application.
Millet	50-75% D	1.2-3.0(d)	
	75% WP	1.95-2.0(s)	
	50% WP/D		
	3-4 lb/gal FlC		
	75% D	2.15-3.0(mai,s)	
	43% WP		
	70% WP	0.93 oz/bu(mai,s)	
	70% WP/D		
Muskmelons	43% WP	1.505(d)	
Oats	37.5% WP/D	0.75(d,s,sp)	
	1.67 lb/gal (17%) RTU	0.63-0.835(s)	
Onion	50-75% D	3.0(d)	
	75% WP/D	3.0-3.15(s)	
	3-4 lb/gal FlC		
	75% D	3.0(mai,s)	
	3 lb/gal FlC	1.86	Unspecified method of application.
	50-75% D	8 oz/10 lb seed (sets)(d)	
	75% WP	or 8 oz/lb pelleted seed(d)	
Peanuts	25-75% D	2.25-2.275(d)	
	75% WP	2.252.36(s)	
	50%		
	3-4 lb/gal FlC		
	75% D	1.5-2.25(mai,s)	
	43-70% WP		
	37.5-70% WP/D		

	43% WP 4 lb/gal FlC	1.72(d) 1.5(s)	Tank mix with 2,6-dichloro-4-nitroaniline; or 2,6-dinitro-4-nitroaniline and carboxin.
Peas	25-75% D 75% WP 50% WP/D 2.9-4 lb/gal FlC	1.5-1.65(d) 1.5-1.575(s)	
	75% D 43-70% WP 70% WP/D	1.41-1.61(mai,s)	
Rice	50-75% D 75% WP 50% WP/D	2.15-2.25(d) 1.25-3.29(s)	
	75% D 70% WP 70% WP/D 1.67 lb/gal (17%) RTU	0.63-0.835(mai,s)	
	2.9-3.8 lb/gal FlC	0.75	Unspecified method of application
	75% WP	6.0(s)	Use is limited to CA; apply as a slurry to water-seeded rice.
	3-4 lb/gal FlC	1.875-2.0(s)	Use is limited to CA; apply as a slurry prior to preplant soaking.
Rye	50-75% D 75% WP 50% WP/D 2.9-4 lb/gal FlC	1.85(d) 0.98-1.95(s)	
	70% WP 70 WP/D	0.93 oz/bu(mai,s)	

Safflower	50-75% D	2.0(d)	
	50% WP/D	2.0-2.1(s)	
	3-4 lb/gal FlC		
	43% WP	1.935(mai,s)	
	70% WP	0.93 oz/bu(mai,s)	
	70 WP/D		
	3 lb/gal FlC	1.01	Unspecifed method of application.
Sesame	50-75% D	1.5(d)	
	75% WP	1.5-1.575(s)	
	50% WP/D		
	3-4 lb/gal FlC		
	75% D	1.4-1.61(mai,s)	
	43-70% WP		
	70% WP/D		
Small Seeded Legumes	30-75% D	4.0(d)	
	75% WP	2.48-4.2(s)	
	50% WP/D		
	3-4 lb/gal FlC		
	75% D	3.75-4.0(mai,s)	
	70% WP		
	70% WP/D		
	1.22 lb/gal (12.71) RTU	1.83-1.86	Unspecified method of application.
	1.24 lb/gal (13.85%) RTU		
Sorghum	50-75% D	1.2-1.35(d)	
	75% WP	1.27-1.95(s)	
	50% WP/D		
	2.9-4 lb/gal FlC		
	75% D	1.31(mai,s)	
	43% NP	2.15(mai,s)	
	70% WP	0.93 oz/bu(mai,s)	
	70 WP/D		
Soybeans	25-75% D	0.975-1.65(d)	
	65-75% WP	0.73-1.05(s)	
	50% WP/D		
	2.9-4 lb/gal FlC		
	0.98 lg/gal (12.41%) RTU		
	1.15 lg/gal (14.66%) RTU		

	1.2 lg/gal (16.01%) RTU		
	1.22 lg/gal (12.71%) RTU		
	1.24 lg/gal (13.85%) RTU		
	75% D		
	43-70% WP	0.8-1.075(mai,s)	
	0.53 lb/gal (5.7%) RTU		
	1.67 lb/gal (17%) RTU		
Sugar Beets	50-75% D	4.0(d)	
	50% WP	4.0-4.2(s)	
	3-4 lb/gal FlC		
	75% D	4.0(mai,s)	
	3 lb/gal FlC	2.48	Unspecified method of application.
Sunflower	3 lb/gal FlC	1.03(s)	
Tomato	50-75% D	3.0(d)	
	75% WP	3.0-3.15(s)	
	50% WP/D		
	3-4 lb/gal FlC		
	75% D	4.0(mai,s)	
	70% WP	2.8(mai,s)	
	70% WP/D		
	43% WP	0.86(mai,s)	
	3 lb/gal	1.86	Unspecified method of application.
Wheat	50-75% D	1.65(d)	
	50% WP/D	1.65-1.725(s)	
	3-4 lb/gal FlC		
	43-70% WP	0.63-1.72(mai,s)	
	37.5-70% WP/D		
	1.67 lb/gal (17%) RTU		
	2.9-3.8 lb/gal FlC	0.92-0.95	Unspecified method of application.

---

[a] Rate given as oz ai/100 lb seed unless otherwise specified; d = dry treatment, s = slurry treatment, sp = spray treatment, mai = multiple active ingredient formulation.

Use Pattern Statement

Thiram may only be used for formulation into products intended for those uses listed in F.3 above. For more detailed use-pattern information on all registered uses of Thiram (both single active and multiple active ingredient products) refer to the EPA Compendium of Registered Pesticides, Volume II: Fungicides and Nematicides, pp. T-30-01 to T-30-09 (Issued: 1975); and/or USDA Compilation of Registered Uses of Fungicides and Nematicides, pp. T-30-01 to T-30-09 (issued 1978); and/or EPA Index to Pesticide Chemicals for Thiram (Issued: 09-07-82, 45 pp.).

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

---

1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

---

*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,C,D,E,F,G,H	No	-	Yes (6 months)
81-2 - Dermal LD_{50}	TGAI	A,B,C,D,E,F,G,H	No	-	Yes (6 months)
81-3 - Inhalation LC_{50} - Rat	TGAI	A,B,C,D,E,F,G,H	No	-	Yes (6 months)
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,C,D,E,F,G,H	No	-	No
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-Rodent	TGAI	A,C,E	No	-	Yes 18 months
82-2 - 21-Day Dermal	TGAI	-	No	-	No
82-3 - 90-Day Dermal	TGAI	-	No	-	No
82-4 - 90-Day Inhalation - Rat	TGAI	-	No	-	No
82-5 - 90-Day Neurotoxicity-Hen/Mammal	TGAI	-	No	-	No

TABLE A

GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,C,E	No	-	Yes (36 months)
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,C,E	No	-	Yes (36 months)
83-3 - Teratogenicity - 2 species	TGAI	A,C,E,	No	-	Yes (36 months)
83-4 - Reproduction, 2-generation	TGAI	A,C,E	No	-	Yes (24 months)
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,C,E	No	-	Yes (12 months)
84-2 - Chromosomal Aberration	TGAI	A,C,E	No	-	Yes (12 months)
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,C,E	No	-	Yes (12 months)

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,C,E	No	-	Yes (18 months)
85-2 - Domestic Animal Safety	Choice	-	No	-	No

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice - Choice of several test substances determined on a case-by-case basis.

2/ The use patterns are coded as follows; A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the time indicated under this column from the time of receipt of this Standard.

TABLE A

GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry [I. EPA Reg. Nos. 352-114 (98.5%T) and 4581-258 (99%T)[a]]				
Product Identify and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	GS0122006, GS0122007 GS0122008 GS0122010	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially[e]	GS0122009	Yes
61-3 - Discussion of Formation of Impurities	TGAI	No	GS0122011, GS0122013	Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	GS0122009, GS0122010	No
63-3 - Physical State	TGAI	Yes	GS0122009, GS0122010	No
63-4 - Odor	TGAI	Yes[f]	GS0122010	Yes
63-5 - Melting Point	TGAI	Yes	GS0122009, GS0122010	No
63-6 - Boiling Point	N/A[d]	N/A		No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	GS0122009, GS0122010	No

a The technical (T) products also serve as manufacturing-use products.
b Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
c Data must be submitted no later than 6 months from the date of this Standard.
d Not required because the 98.5% technical is a solid at room temperature.
e Not satisfied for EPA Reg. No. 4581-258 (99% T).
f Not satisfied for EPA Reg. No. 352-114 (98.5% T).

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry [I. EPA Reg. Nos. 352-114 (98.5%T) and 4581-258 (99%)[a] (Continued)				
63-8 - Solubility	TGAI or PAI	Yes[d]	GS0122011	No
63-9 - Vapor Pressure	PAI	No		Yes
63-10 - Dissociation Constant	PAI	No		Yes
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	Partially[e]	GS0122011	Yes
Other Requirements:				
64-1 - Submittal of samples	N/A	N/A		No

---

a The technical (T) products also serve as manufacturing-use products.
b Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
c Data must be submitted no later than 6 months from the date of this Standard.
d Partially satisfied for EPA Reg. No. 4581-258 (99% T.).
e Not satisfied for EPA Reg. No. 352-114 (98.5% T).

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry [II. EPA Reg. Nos. 1187-131 (98.5%T) and 8236-2 (99%T)][a]				
Product Identify and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	GS0122016, GS0122017 GS0122014, GS0122018 GS0122019	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No[d]	GS0122020, GS0122017 GS0122015	Yes
61-3 - Discussion of Formation of Impurities	TGAI	No[e]	GS0122020 GS0122021	Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	GS0122014, GS0122015	No
63-3 - Physical State	TGAI	Yes	GS0122020, GS0122021	No
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	No		Yes
63-6 - Boiling Point	N/A[f]	N/A		No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	GS0122014, GS0122020	No

a The technical (T) products also serve as manufacturing-use products.

b Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.

c Data must be submitted no later than 6 months from the date of this Standard.

d Partially satisfied for EPA Reg. No. 1187-131 (98.5% T).

e Fully satisfied for EPA Reg. No. 1187-131 (98.5% T).

f Not required because the 98.5% technicals are solid at room termperature.

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry [II. EPA Reg. Nos. 1187-131 (98.5%T) and 8236-2 (99%T)[a] (Continued)				
63-8 - Solubility	TGAI or PAI	No		Yes
63-9 - Vapor Pressure	PAI	No		Yes
63-10 - Dissociation Constant	PAI	No		Yes
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	Yes	GS0122014, GS0122020	No
63-13 - Stability	TGAI	No[d]	GS0122020	Yes
Other Requirements:				
64-1 - Submittal of samples	N/A	N/A		No

a The technical (T) products also serve as manufacturing-use products.

b Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.

c Data must be submitted no later than 6 months from the date of this Standard.

d Partially satisfied for EPA Reg. No. 1187-131 (99.5% T.).

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry [III. EPA Reg. Nos. 1965-43 (97%T) and 45728-1 (98.5%T)[a]]				
Product Identify and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	GS0122016, GS0122012	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No		Yes
61-3 - Discussion of Formation of Impurities	TGAI	No[d]	GS0122015, GS0122014	Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	No		Yes
63-3 - Physical State	TGAI	No		Yes
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	No		Yes
63-6 - Boiling Point	N/A[e]	N/A		No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes

[a] The technical (T) products also serve as manufacturing-use products.
[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Fully satisfied for EPA Reg. No. 45728-1 (98.5% T).
[e] Not required because the technicals are solids at room temperature.

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry [III. EPA Reg. Nos. 1965-43 (97%T) and 45728-1 (98.5%T)[a]] (Continued)				
63-8 - Solubility	TGAI or PAI	No		Yes
63-9 - Vapor Pressure	PAI	No		Yes
63-10 - Dissociation Constant	PAI	No		Yes
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	No		Yes
Other Requirements:				
64-1 - Submittal of samples	N/A	N/A		No

[a] The technical (T) products also serve as manufacturing-use products.

[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.

[c] Data must be submitted no later than 6 months from the date of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	GS0122036, 05003661 GS0122024,	Yes[3]
- Livestock	PAIRA and plant metabolites	No	GS0122037	Yes[4]
171-4 - Residue Analytical Method				
- Plant residues	Pure Analtyical Standard and metabolites	Partially	Footnote A	Yes[5]
- Animal residues Presently there are no established tolerances	Pure Analytical Standard and metabolites	N/A	GS0122037	Yes[17]
171-4 - Storage Stability Data	PAI	No		Yes[6]

A. Bibliographic citations: GS0122022, 00002931, 00098135, GS0122023, 00098644, GS0122024, GS0122025, GS0122026, GS0122027, GS0122028, GS0122029, GS012230, GS0122031, 00085531, GS0122032, GS0122033, 00045166, 00090174, GS0122034, GS0122035, 00098137, GS0122039

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residues Studies for Each Food Use				
o Onions (dry bulb)	EP	Partially	GS0122038, 00041997	Yes[7]
o Celery	EP	Partially	00098190, 00090158 00090157	Yes[8]
o Tomatoes	EP	Partially	00098190	Yes[9]
o Apples	EP	Partially	00089610, 00098190	Yes[10]
o Peaches	EP	Partially	00098132, 00089409 00075880	Yes[11]
o Strawberries	EP	Partially	00097049, 00098142	Yes[12]
o Bananas	EP	Partially	00098143, 00047581 00098137	Yes[13]
o Cotton	EP			Yes[14]
o All seed uses	EP	No		Yes[15]
o Meat/milk/poultry/eggs	TGAI or Plant Metabolites	No		Yes[16]

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

§158.125 Residue Chemistry (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active iingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted no later than 24 months from the date of receipt of this Standard.

3/ Studies concerning the uptake, metabolism and translocation of [^{14}C] thiram by a small grain crop, a root crop, and a leafy vegetable. (*Note the thiocarbamate carbon should be labeled.) Plants must be planted in treated soil ar the same plants must subsequently be treated foliarly. Radioactive residues must be characterized and quantified in grain, roots, and foliage. A method such as GC or HPLC msut be used followed by verification by MS.

Studies concerning the uptake and translocation of [^{14}C] thiram into a small grain, cotton, and soybeans following planting of seed treated with [^{14}C] thiram at the respective maximum registered rates. Total radioactivity must be quantified in all plant parts at various stages of growth, including the forage stage and at harvest of the raw agricultural commodity. This study is necessary to determine whether thiram seed treatments may continue to be considerd nonfood uses or whether tolerances (and the requisite residue data) are required for the commodities derive from these crops. [Refer to the section concerning seed treatments.]

4/ Metabolism studies utilizing lactating ruminant dosed with [^{14}C] thiram at 7 ppm (or more, if necessary, to obtain sufficient metabolite levels for identification) in the diet for 3 days. (*Note the thiocarbamate should be labeled. Animals must be sacrificed within 24 hours of the final dose and residues must be characterized and quantified in mil muscle, fat, kidney, and liver. Milk must be sampled twice daily throughout the dosing period.

Poultry metabolism studies in which laying hens are dosed with [^{14}C] thiram at 0.6 ppm (or more, if necessary, to obtain sufficient metabolite levels for identification) in the diet for 3 days. Animals must be sacrificed within 24 hours of the final dose and residues must be characterized and quantified in eggs, muscle, fat, gizzard, heart, liver and skin. Eggs must be sampled twice daily throughout the dosing period.

5/ A validated method (preferably GC) which can be used to enforce the established tolerances for residues of thiram per se in or on apples, celery, peaches, strawberries, tomatoes, bananas, snd onions.

A validated confirmatory method (preferably MS).

(It should be noted that the available plant metabolism data are sufficient. Should the required metabolism data reveal additional metabolites of concern adequate regulatory methods may be required. Also, the available plant metabolism data, though insufficient, indicate that residues will not be restricted to the surfaces of treated crops. Surface stripping extraction procedures will be unacceptable.)

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

6/ Data demonstrating the stability of thiram residues in or on representative plant and animal samples stored at freezing temperatures for intervals up to 1 year or for a period approximately that used for the residues studies which follow or those requested.

7/ Residue data involving thiram residues in or on dry bulb onions following the in-furrow application at-planting of either a 65-75% WP or 5-7.5% G formulation at 2.06 lb ai/A (36-inch row spacing) from tests conducted in western states. See discussion below concerning green onions.

The requirement for data involving thiram studies in or on onions as the result of seed treatments will be dependent upon results of the requested plant metabolism data (see plant metabolism section), which would qualify such seed treatments as either non-food uses or food uses. Additionally, unless removal of green onions from the existing 5% G formulation labels is considered appropriate, we recommend the proposal of a green onion tolerance and the requirement of residue data reflecting use of this formulation for green onions as an in-furrow treatment at-planting at 2.06 lb ai/A from geographically representative test locations. The Mexican tolerances for residues of thiram per se in or on onions has been established at 0.5 ppm. No Canadian tolerance or Codex MRL exists for thiram residues in or on onions. Use of the 5% G formulations on green onions (this would qualify as a food use) is not supported by any submitted data; nor has a tolerances been established for thiram residues in or on green onions. Unless the registrant opts for removal of green onions from the existing labels, submission of data pertaining to the use of thiram formulations on greeen onions and the level of residues contained therein as well as the subsequent establishment of a green onion tolerance will be necessary.

8/ Residue data from trimmed and washed mature celery from plants which were treated before transplanting with the 4 lb/gal FlC and, in a separate test, a representative WP formulation at 0.25 lb ai/1,2000 square feet (9.08 lb ai/A), at least four times at 3-day intervals. The studies should take place in CA, which produces 69% of the U.S. celery crop (Agricultural Statistics, 1982, p. 158).

Residue data from trimmed and washed mature celery raised from transplants foliarly-treated four times at 0.25 lb ai/1,2000 square feet (9.08 lb ai/A), and, after transplanting, treated at least 20 times at 2.1 lb ai/A with a representative WP formulation at 3-7 day intervals. These tests should take place in FL (since the latter treatment is registered in FL only).

9/ Data reflecting residues on the day of the last of 20 foliar applications (3-5 day intervals) with one of the WP formulations and at 1.125 lb ai/100 gal and the 3.3% D formualtion at 1 lb ai/A. FlC and WP data should represent the maximum expected dosage rate (ai/A) based on typical commercial row spacings and volume of spray/A. Tests should be conducted in CA(29%) and FL(42%); the contribution to U.S. fresh market tomato production, as designated in Agricultural Statistics, 1982, p. 176, is given parenthetically.

Data pertaining to thiram residues in or the processed products of tomatoes (pomace, puree, catsup, and juice) processed from field-treated tomatoes which contain measurable weathered residues.

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

10/ Residue data from apples treated at least 10 times at 2.6 lb ai/A with a representative D formulation and the 65% WP (prepared as a D formulation) both aerially and ground-applied (separate tests), sampled on the day of the last treatment. The studies should take place in NY and WA.

Residue data from apples treated at least 10 times at 1.3 lb ai/100 gal with 65% WP, sampled on the same day as the last treatment. The studies should take place in NY and WA.

Residue data from apples harvested on the same day of the last of at least 10 treatments with the 4 lb/gal FlC at 1.3 lb ai/100 gal (sprayed to runoff). The studies should take place in NY and WA.

Residue data from apples and appropriate processed apple products (wet pomace, dry pomace and juice) produced upon processing of apples having weathered residues at or above the tolerance. This may require that the apples be treated at exaggerated rates.

11/ Residue data at 7 days posttreatment reflecting 5 applications of 3-day intervals during blossom development and 12 applications at 10-day intervals beginning at petal fall. The following formulations must be applied: 65-95% WP and 4 lb/gal FlC (at 1.3 lb ai/100 gal); 3.41 lb ai/A of a representative D formulation. Tests should involve both aerial and ground applications and must be conducted in CA, PA, and SC. The number of gallons of spray material applied (FlC and WP per acre must be specified and must reflect good agricultural practices.

A temporary Codex MRL of 3 ppm has been established for dithiocarbamate residues (including thiram) in or on peaches expressed as ppm CS_2. The Canadian and Mexican tolerances are identical to the U.S. tolerance. Compatibility between the U.S. tolerances and Codex MRL will not be assessed until receipt of the requested data.

12/ Data reflecting residues at daily intervals from 0-7 day following the last of five foliar applications at 10-day intervals with the 7.5% D and 4 lb/gal FlC formulations at 3 and 3.25 lb ai/application, respectively. Tests must be conducted in CA and FL, which respectively produce 7.3% and 9% of the U.S. strawberry crop (Agricultural Statistics, 1982, p. 229). If necessary, PHIs must be proposed.

13/ Residue data involving thiram residues in or on whole bananas and the pulp from the use of the 65% WP. Three preharvest applications must be made at weekly intervals beginning at flower emergence at 0.65 lb ai/5 gal. Tests must be conducted in two or more of the following countries: Guatemala, Nicaragua, Costa Rica, Panama, Columbia, or Ecuador.

Residue data involving thiram residues in or on whole bananas and the pulp from the use of the 0.1% RTU formulation applied postharvest as a 0.1% ai paste brushed on crown areas (formulated with ziram, sodium O-phenylphenate, and sulfur.

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

14/ Because no tolerance exists for thiram residues in or on cotton, no conclusions can be made at this time. However, unless in-furrow treatment (considered a food use) are removed from the existing labels, the proposal of such a tolerance will be necessary as will the submission of data involving thiram residues in or on cotton (and, perhaps, cottonseed products), as a result of in-furrow treatments. Seed treatment data may also be required pending results of requested plant metabolism studies (uptake of residues into plants grown from thiram-treated seed).

15/ As no residue data were submitted that reflect seed treatment and knowledge of the plant metabolism of thiram is incomplete, we cannot determine the necessity for tolerances for thiram residues in or on crops treated in this manner. When the data requirements outlined in the Nature of the Residue section are completed we will be able to assess the need for these tolerances and accordingly, for each crop let stand their non-food status, or required appropriate residue data and tolerance proposals.

16/ The following feeding studies will be required, but only if the requested animal metabolism studies reveal that thiram residues of concern transfer to animal products:

Lactating ruminants must receive thiram in the diet at 2.5, 10.5 and 35 ppm for 4 weeks or until residue plateau in milk. All residues of concern must be quantified in milk (collected twice daily), liver, and fat. If the requested plant metabolism studies reveal that one or more residues of concern other than thiram *per se* occur in or on feed items, then these metabolites must also be fed to the same animals receiving thiram *per se* at levels proportionate to their occurrence in or on feed items.

Laying hens must receive thiram in the diet at 0.6, 1.8, and 6.0 ppm for 4 weeks or until residues plateau in eggs. All residues of concern must be quantified in eggs (collected twice daily), fat, gizzard, liver, muscle, and skin. As noted above for ruminants, other residues of concern found in or plants if they exist, must be fed.

17/ If the animal metabolism studies reveal that thiram residues of concern transfer to animal derived raw agricultural commodities and if feeding studies indicate that animal tolerances are needed then validated enforcement methods for identification and quantification of the residue will be required.

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,E,F,H	No	-	Yes (6 months)
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B,C,	No	-	Yes (6 months)
161-3 - On soil	TGAI or PAIRA	A,B,C,	No	-	Yes (6 months)
161-4 - In air	TGAI or PAIRA	A,B,C,	No	-	Yes[4] (6 months)
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,C,E,F,H	No	-	Yes (2 years)
162-2 - Anaerobic Soil	TGAI or PAIRA	A,B,C,	No	-	Yes[8] (2 years)
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	No	-	Yes (2 years)
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No	-	Yes (2 years)
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,E,F,H	No	-	Yes (6 months)
163-2 - Volatility (Lab)	TEP	A,B,C,E,F	No	-	Yes[4] (6 months)
163-3 - Volatility (Field)	TEP	A,B,C,E,F	No	-	Yes[4] (6 months)

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B,C,H	No	-	Yes (2 years)
164-2 - Aquatic (Sediment)	TEP	C	No	-	Yes (2 years)
164-3 - Forestry	TEP	None	No	-	yes[4]
164-4 - Combination and Tank Mixes	-	-	No	-	No[5]
164-5 - Soil, Long-term	TEP	A,B,C,E,F,H	No	-	Yes (4 years)
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A,B,C	No	-	Yes (4 years)
165-2 - Rotational Crops (Field)	TEP	A,B,C	No	-	Yes (4 years)
165-3 - Irrigated Crops	TEP	C	No	-	Yes (4 years)
165-4 - In fish	TGAI or PAIRA	A,B,C	No	-	Yes (4 years)
165-5 - In Aquatic Non-Target Organisms	TEP		No	-	No[7]

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.130 Environmental Fate (continued)					
Subpart K Re-entry					
132-1 Foliar Dissipation	TEP	A,B,C	No	-	Yes (2 years)
132-1 Soil Dissipation	TEP	A,B,C	No	-	Yes (2 years)
133-3 Dermal Exposure	TEP	A,B,C	No	-	Yes (2 years)
133-4 Inhalation Exposure	TEP	A,B,C	No	-	Yes (2 years)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows; A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within time indicated under column from date of receipt of this Standard.
4/ Not required because thiram has no forestry use.
5/ Not required because this Standard only deals with single active ingredient products.
6/ May be required, depending on results from 164-1, 164-2 and 162-1. If required, must be submitted within 4 years after notified of the need.
7/ May be required, depending on results from 165-4.

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sectio 3(c)(2)(B)?3/
§158.145 Wildlife and Aquatic Organisms					
Avian and Mammalian Testing					
71-1 Avian Oral LD_{50}	TGAI	A,B,H	Yes	00073683 GS0122040	No
71-2 Avian Dietary LC_{50}	TGAI				
a. waterfowl		A,B,H	Yes	00034769	No
b. upland game		A,B,H	Yes	00034769	No
71-3 Wild Mammal Toxicity	TGAI	A,B,H	No		
71-4 Avian Reproduction	TGAI	A,B,H	Partially	GS0122041 00103373	Yes 4/ (12 month
71-5 Simulated and Actual Field Testing for Mammals and Birds	TEP	A,B,H	No		Reserved 5/
Aquatic Organism Testing					
72-1 Freshwater Fish LC_{50}					
a. warmwater	TGAI TEP	A,B N/A 6/	Yes Yes	GS0122042 00090294	No No
b. coldwater	TGAI TEP	A,B N/A 6/	Yes Yes	GS0122043 00090293	No No
72-2 Acute LC_{50} - Freshwater Invertebrates	TGAI	A,B	No		Yes (6 months

TABLE A (Con't)
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
72-3 Acute LC_{50} - Estuarine and Marine Organisms	TGAI	A,B	No		Reserved 5/
72-4 Fish Early Life Stage and Aquatic Invertebrate Life-cycle	TGAI	A,B	No		Reserved 5/
72-5 Fish Life-cycle	TGAI	A,B	No		Reserved 5/
72-6 Aquatic Organism Accumulation	TGAI PAI or Degradation Product	A,B	No		Reserved 5/
72-7 Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,B	No		Reserved 5/

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows; A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted within time indicated under column from date of receipt of this Standard.
4/ Protocols for avian reproduction studies must be submitted to EEB for approval prior to conducting the tests.
5/ Requirement is reserved pending a review of outstanding ecological effects and environmental fate data.
6/ Not applicable at this time.

* Study on its own fulfills guideline requirements.
** Study must be combined with other studies to fulfill guideline requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}q	TGAI	A,B,G,H	Yes	00036935	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,G,H	No	______	No[4]
141-4 - Honey bee sub-acute feeding study	[Reserved] 5/				
141-5- Field testing for pollinators	TEP	A,B,G,H	No	______	No[4]

TABLE A
GENERIC DATA REQUIREMENTS FOR THIRAM

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects		A,B,G,H	No	-	6/
142-2 - Aquatic insect life-cycle study		A,B,G,H	No	-	6/
142-3 - Simulated or actual field testing for aquatic insects		A,B,G,H	No	-	6/
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES		A,B,G,H	No	-	6/

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows; A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted no later than [date to be established if data are required in the future].

4/ As acute contact LD_{50} test showed thiram to be non-toxic to honey bees, no further testing is required.

5/ Reserved pending development of test methodology.

6/ Reserved pending Agency decision as to whether the data requirement should be established.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This Section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

---

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING THIRAM

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
EPA Reg. Nos 2749-12 (65% FI), 2749-10 (72% FI), 2749-79 (80% FI), and 2749-11 (99.45% FI)[a]				
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Indentity and Disclosure of Ingredients	MP	Yes	GS0122001 thru GS0122004	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No[d]	GS0122004	Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	GS0122005	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	GS0122022	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

a/ FI = formulation intermediate.
b/ Composition: MP = Manufacturing-use product.
c/ Data must be submitted no later than 6 months from the date of this Standard.
d/ Partially satisfied for EPA Reg. No. 2749-11 (99.45% FI).

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING THIRAM

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c) (2) (B) ?[c]
EPA Reg. Nos. 1965-43 (97% T), 8236-2 (97% T), 4581-258 (99% T), 2749-12 (65% FI), 2749-10 (75% FI), 2749-70 (80% FI), and 2749-11 (99.45% FI)[a]				
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	GS0122001 thru GS0122004 GS0122010 and GS0122012	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No[d]	GS0122055 and GS0122007	Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	GA0122005 and GS0122009	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	GA0122022	Yes
Other Requirements:				
64-1 - Submittal of Samples	MP	N/A		No

a/ The technical products (T) also serve as manufacturing-use products; FI = formulation intermediate.
b/ Composition; MP = Manufacturing-use product.
c/ Data must be submitted no later that 6 months from the date of this Standard.
d/ Partially satisfied for EPA Reg. No 2749-11.

TABLE B

PRODUCT SPECIFIC DATA REQUIRAEMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING THIRAM

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
EPA Reg. NOs. 352-114, 1187-131, and 45728-1 (98.5% T)[a]				
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	GS0122008, GS0122010, GS0122016	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	Partially	GS0122009, GS0122017	Yes
61-3 - Discussion of Formation of Impurities	MP	Yes[d]	GS0122011, GS0122017	
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of ingredient Limits	MP	Partially	GS0122009, GS0122017	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	GS0122022	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

a/ The 98.5 % technicals (T) also serve as manfacturing-use products.
b/ Composition: MP = Manufacturing-use product.
c/ Data must be submitted no later than 6 months from the date of this Standard.
d/ Not satisfied for EPA Reg. No. 352-114.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING THIRAM

Data Requirement	Composition [1]	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} -Rat	MP	No	-	Yes (6 months)
81-2 - Dermal LD_{50}	MP	No	-	Yes (6 months)
81-3 - Inhalation LC_{50} - Rat	MP	No	-	Yes (6 months)
81-4 - Primary Eye Irritation - Rabbit	MP	No	-	Yes (6 months)
81-5- Primary Dermal Irritation	MP	No	-	Yes (6 months)
81-6 - Dermal Sensitization	MP	No	-	Yes (6 months)

---

[1] Composition: MP = Manufacturing-use product.
[2] Data must be submitted within the time indicated under this column from date of receipt of this Standard.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies to end-use products only to the extent described under Section II of this document. Otherwise, the following information pertains exclusively to manufacturing-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix IV-1 and IV-2], as indicated by the following paragraphs of this chapter of the guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this Section and/or Section II, EPA may issue a notice of intent to cancel the registration under FIFRA §6(b)(1).

A. Label Contents

40 CFR §162.10 (Appendix IV-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table entitled: "Labeling Requirements of FIFRA, As Amended".

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix IV-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix IV-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix IV-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR §162.10 (n)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR §162.10(n)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix IV-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Henry M. Jacoby, Product Manager 21
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-1900

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

   d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, the registrant may submit such labeling. (End-use product labeling needs to comply specifically with the instruction in Section II of this guidance document.) The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for stortage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

After the Supreme Court has ruled on the Monsanto Decision, you will be informed as to when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the associated data support information.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Thiram Standard

00002931 Keppel, G.E. (1971) Collaborative study of the determination of Dithiocarbamate residues by a modified Carbon disulfide evolution method. Journal of the AOAC Association of Official Analytical Chemists 54(3):528-531. (Also in unpublished submission received on unknown date under 0F0939; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:094582-G)

00034769 Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds. By U.S. Fish and Wildlife Service, Patuxent Wildlife Research Center. Washington, D.C.: U.S. FWS. (Special Scientific Report--Wildlife No. 191; report no. 33423a; also in unpublished submission received Mar 28, 1979 under 3125-236; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:237905-B)

00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)

00041997 Ryker, T.C. (1970) Letter sent to C.C. Compton dated Jun 26, 1970: Thiram residues in onions. (Unpublished study received Nov 1, 1970 under 1E1123; prepared by E.I. du Pont de Nemours & Co., submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:090898-A)

00045166 Pease, H.L. (1953?) Determination of Dithiocarbamate Fungicide Residues. Undated method. (Unpublished study received Aug 20, 1957 under PP0144; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:092424-G)

00047581 E.I. du Pont de Nemours & Company, Incorporated (1968) Residue Data Thiram--Bananas. (Unpublished study received Sep 10, 1968 under 9F0758; CDL:093070-B)

00073683 Schafer, E.W. (1972) The acute oral toxicity of 369 pesticidal, pharmaceutical and other chemicals to wild birds. Toxicology and Applied Pharmacology 21:315,316,319. (Incomplete; also in unpublished submission received Mar 21, 1977 under 352-338; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:228727-AI)

00075880 E. I. du Pont de Nemours & Company (1955) Results of tests on the Amount of Residue Remaining on Apples: [Thiram]. (Unpublished study received on unknown date under PP0052; CDL:090050-B)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Thiram Standard

00085531 Lacy, M.L. (1970) Letter sent to C.C. Compton dated Nov 30, 1970 [Determination of Thiram residues in onions]. Unpublished study received Nov 1, 1970 under 1E1123; prepared by Michigan State Univ., Dept. of Botany and Plant Pathology, submitted by Interregional Research Project No. 4, New Brunswich, N. J.; CDL:090898-B)

00089409 E.I. du Pont de Nemours & Company (1958) Additional Data in Support of Petition: Summary: Thiram. (Compilation; unpublished study, including published data, received Dec 15, 1958 under PP0204; CDL:090232-B)

00089610 E.I. du Pont de Nemours & Company, Incorporated (1955) Results of Tests on the Amount of Residue Remaining on Apples: Thiram. Includes method dated Dec 9, 1954. (Unpublished study received Feb 25, 1955 under PP0009; CDL:090009-D)

00090157 E.I. du Pont de Nemours & Company, Incorporated (1960) Results of Tests on the Amount of Residue Remaining on Celery: [Thiram], (Unpublished study received Oct 20, 1960 under PP0278; CDL: 090300-A)

00090158 E.I. du Pont de Nemours & Company, Incorporated (1960) Control of Certain Diseases of Celery with Thylate Thiram Fungicide and Combinations of Thylate with Manzate Maneb Fungicide or Parzate C Zineb Fungicide. (Compilation; unpublished study received Oct 20, 1960 under PP0278; CDL:090300-B)

00090174 Pease, H.L. (1957) Determination of dithiocarbamate fungicide residues. Journal of the Association of Official Agricultural Chemists 40(4):1113-1118. (Also in unpublished submission received Oct 20, 1960 under PP0278; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:090300-C)

00090293 McCann, J.A. (1972) Tersan 75: Rainbow Trout (Salmo gairdneri): Test No. 463. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130512-A)

00090294 McCann, J.A. (1972) Tersan 75: Bluegill (Lepomis macrochirus): Test No. 446. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130513-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Thiram Standard

00097049 E.I. du Pont de Nemours & Company, Incorporated (1957) Summary of Thiram and Dithiocarbamate Residue Data on Strawberries. (Unpublished study received Jan 8, 1957 under unknown admin. no.; CDL:124402-D)

00098132 E.I. du Pont de Nemours & Company, Incorporated (1956) Results of Tests on the Amount of Residue Remaining on Peaches: Thiram. (Unpublished study received Sep 1, 1956 under PP0091; CDL: 090121-A)

00098135 Breault, E.A. (1960) Letter sent to H.W. Gerritz dated Dec 13, 1960: Thiram (tetramethyl thiuram disulfide) on celery. (U.S. Government; unpublished study; CDL:092556-A)

00098137 Rosen, D.E. (1962) Letter sent to William Stokes dated May 22, 1962 Thiram fungicide residues in bananas. (Unpublished study received on unknown date under PP0359; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:092643-A)

00098142 E.I. du Pont de Nemours & Company, Incorporated (1959) Thiram: Residues in Peaches and Strawberries. (Compilation; unpublished study received on unknown date under PP0204; CDL: 098740-A)

00098143 E.I. du Pont de Nemours & Company, Incorporated (19??) Residue (ppm): Thiram: Whole Fruit. (Unpublished study received on unknown date under PP0359; CDL:098907-A)

00098190 E.I. du Pont de Nemours & Company, Incorporated (1957) Results of Tests on Amount of Residue Remaining on Food Crops: Thiram. Includes undated method entitled: Determination of dithiocarbamate fungicide residues. (Compilation; unpublished study received Aug 4, 1957 under PP0144; CDL:090172-C)

00098644 Cullen, T.E. (1964) Spectrophotometric determination of dithiocarbamate residues on food crops. Analytical Chemistry 36(1): 221-224. (Also in unpublished submission received Nov 16, 1965 under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL:120299-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Thiram Standard

00103373	Midwest Research Institute (1977) Initial Scientific Review of Thiram: MRI Project No. 4307-L; RvR Project No. 78. (Unpublished study received Jun 15, 1982 under unknown admin. no.; prepared in cooperation with RvR Consultants, submitted by Bonide Chemical Co., Inc., Yorksville, NY; CDL:247670-A)
05003661	Solel, Z.; Edgington, L.V. (1973) Transcuticular movement of fungicides. Phytopathology 63(4):505-510.

Appendix II-1

BIBLIOGRAPHY
THIRAM REGISTRATION STANDARD
Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

GS0122001 U.S. EPA (undated) Registration Jacket for Thiram 65, EPA Registration No. 2749-12, Statement of ingredients received 2/20/67.

GS0122002 U.S. EPA (undated) Registration Jacket for Thiram 75, EPA Registration No. 2749-12, Statement of ingredients received 2/20/67.

GS0122003 U.S. EPA (undated) Registration Jacket for Thiram 80% Wettable Powder, EPA Registration No. 2749-79, Statement of ingredients received 11/20/70.

GS0122004 U.S. EPA (undated) Registration Jacket for Thiram 100 Fungicide, EPA Registration No. 2749-11, Statement of ingredients received 3/17/75.

GS0122005 U.S. EPA (undated) Registration Jacket for Thiram 100 Fungicide, EPA Registration No. 2749-11, Data in correspondence received 5/20/75.

GS0122006 U.S. EPA (undated) Registration Jacket for Pennwalt Thiram Technical, EPA Registration No. 4581-258, Memorandum from Richard Loranger to Henry Jacoby dated 10/6/81.

GS0122007 U.S. EPA (undated) Registration Jacket for DuPont Thiram Technical, EPA Registration No. 352-114, Composition of DuPont Thiram Technical dated 11/8/68.

GS0122008 Ibid., Confidential Statement of Formula received 2/7/77.

GS0122009 Ibid., General Chemistry Data on DuPont Thiram Technical dated 2/4/77.

GS0122010 U.S. EPA (undated) Registration Jacket for Pennwalt Thiram Technical, EPA Registration No. 4581-258, Confidential Statement of Formula dated 5/4/73.

BIBLIOGRAPHY
THIRAM REGISTRATION STANDARD
Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

GS0122011	Ibid., Product Data Bulletin #9a, Thiram Technical received 8/20/73.
GS0122012	U.S. EPA (undated) Registration Jacket for Vancide TM, EPA Registration No. 1965-43, Ingredient Statement dated 10/5/65.
GS0122013	Sittig, Marshall (ed). 1977. Pesticide Process Encyclopedia. Noyes Data Corp. Park Ridge, NJ. p. 464.
GS0122014	U.S. EPA (undated) Registration Jacket for Thiram Technical, EPA Registration No. 8236-2, Formula Data Sheet received 10/29/69.
GS0122015	U.S. EPA (undated) Registration Jacket for Tetramethylthiuram disulfide React-Rite® TMTD, EPA Registration No. 45728-1, Material Safety Data Sheet received 11/24/81.
GS0122016	Ibid., Confidential Statement of Formula dated 5/24/82.
GS0122017	U.S. EPA (undated) Registration Jacket for Thiram Technical, EPA Registration No. 8236-2, Data from a Confidential Statement of Formula dated 11/8/68.
GS0122018	Ibid., Data Sheets for a 97% Thiram Product received 8/27/69 and 10/29/69.
GS0122019	U.S. EPA (undated) Registration Jacket for Thiram Technical, EPA Registration No. 1187-131, Confidential Statement of Formula dated 5/27/82.
GS0122020	Ibid., Information from Product Chemistry Data received 5/27/82.
GS0122021	Ibid., Data from Bulletin Thiram-01 received 2/26/84.

Appendix II-1

BIBLIOGRAPHY
THIRAM REGISTRATION STANDARD
Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

GS0122022	Association of Official Analytical Chemists. 1980. Official Methods of Analysis. 13th Edition. Sections 29.165 - 29.171.
GS0122023	Clarke, D. G., H. Baum, E. L. Stanley, and W. F. Hester. 1951. Determination of dithiocarbamates. Anal. Chem. 23(12):1842-1846.
GS0122024	U.S. EPA 1954. Correspondence File for Pesticide Petition No. 0052 (EPA Accession No. 113119). Method of Analysis for Thiram Residues in Crops.
GS0122025	U.S. EPA 1956. Correspondence File for Pesticide Petition No. 0091 (EPA Accession No. 113251). Determination of Dithiocarbamate Residues on Crops.
GS0122026	Heurmann, R. F. 1957. Determination of residue quantities of dialkydithiocarbamates by amine evolution. J.A.O.A.C. 40(1):264-270.
GS0122027	Keppel, G. E. 1957. Report on tetramethylthiram disulfide (thiram). J.A.O.A.C. 40(1):270-273.
GS0122028	Keppel, G. E. 1959. Report on the determination of tetramethylthiram disulfide (thiram) on corn and apples. J.A.O.A.C. 42(3):545-548.
GS0122029	U.S. EPA 1970. Correspondence File for Pesticide Petition No. 0278 (EPA Accession No. 113804). Memorandum to Chief Chemist, Cincinnati District, pertaining to a method tryout on celery dated 11/29/70.
GS0122030	Keppel, G. E. 1962. Thiram residues in tomatoes, strawberries, and celeries. J.A.O.A.C. 45(2):410-414.
GS0122031	Keppel, G. E. 1969. Modification of the carbon disulfide evolution method for dithiocarbamate residues. J.O.A.C. 52(1):162-167.

Appendix II-1

BIBLIOGRAPHY
THIRAM REGISTRATION STANDARD
Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

GS0122032 Lowen, W. K. 1951. Determination of dithiocarbamate residues on food crops. Anal. Chem. 43(3):717-720.

GS0122033 McKinley, W. P. and S. A. Magarvey. 1960. Paper chromatography of ferbam, maneb, nabam, thiram, zineb, and ziram. J.A.O.A.C. 43(3):717-720.

GS0122034 Pesticide Analytical Manual (PAM), Vol. II. Dithiocarbamates.

GS0122035 Pesticide Analytical Manual (PAM), Vol. II. Pesticide Regulatory Section 180.132.

GS0122036 Dekhuijzen, H. M. 1964. The systemic action of dimethyldithiocarbamates on cucumber scab caused by _Cladosporium cucumerinum_ and the conversion of these compounds by plants. Neth., J. Plant Path. 70(Suppl. 1): 75 pp. [Not registrant-submitted.]

GS0122037 Robbins, R. C., and J. Kasteclic. 1961. Fate of tetramethylthiuram disulfide in the digestive tract of the ruminant animal. J. Agric. Food Chem. 9(4):256-260. [This was not registrant-submitted. Labeled thiram was not used, tissues and milk were not analyzed, data were variable, 95% of the dose was not recovered.]

GS0122038 U.S. EPA 1970. Correspondence File for Pesticide Petition No. 1E1123 (EPA Accession No. 117227). Correspondence to C.C. Compton submitted by IR-4 under Section D dated 11/30/70.

GS0122039 Association of Official Analytical Chemists. 1980. Official Methods of Analysis 13th Edition. Sections 29.165-29.171.

GS0122040 Tucker, R. K. and D. G. Crabtree. (1970). Handbook of toxicity of pesticides to wildlife. Resource Pub: 84, U.S.D.I., Fish and Wildlife Service, Denver Wildlife Research Center. Washington, DC 131 p. (Fiche ID #BAOTHI03).

BIBLIOGRAPHY
THIRAM REGISTRATION STANDARD
Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

GS0122041	Enviro. Control Inc., 1981. Hazard Information review: Bis (dimethylthiocarbamyl) Disulfide. IR-220 Prepared under EPA Contract No. 68-01-5789 (TSCA Interagency testing Committee). (Fiche ID No. BAOTHI04).
GS0122042	McCann, J. A. 1976. Bluegill sunfish (Leponis macrochirus). Test No. 996 (U.S. EPA, Chemical and Biological Investigations Branch, Animal Biology Laboratory). (Fiche ID No. BAOTHI01).
GS0122043	McCann, J. A. 1976. Rainbow Trout (Salmo gairdneri). Test No. 1001 (U.S. EPA, Chemical and Biological Investigations Branch, Animal Biology Laboratory). (Fiche ID No. BAOTHI02).

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	**GUIDANCE DOCUMENT DATE** **ACTIVE INGREDIENT**
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	**DATE OF OFFER**

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	**SIGNATURE**	**DATE**

EPA Form 8580-6 (10-82)

APPENDIX III-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.______________ Guidance Document for______________________

Date______________________

			I am complying with data requirements by		
Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	Citing MRID#	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility		–		
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible, within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or-skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face sheild and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F, if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five~~

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address, and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

~~(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)~~

~~[44 FR 27953, May 11, 1979]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

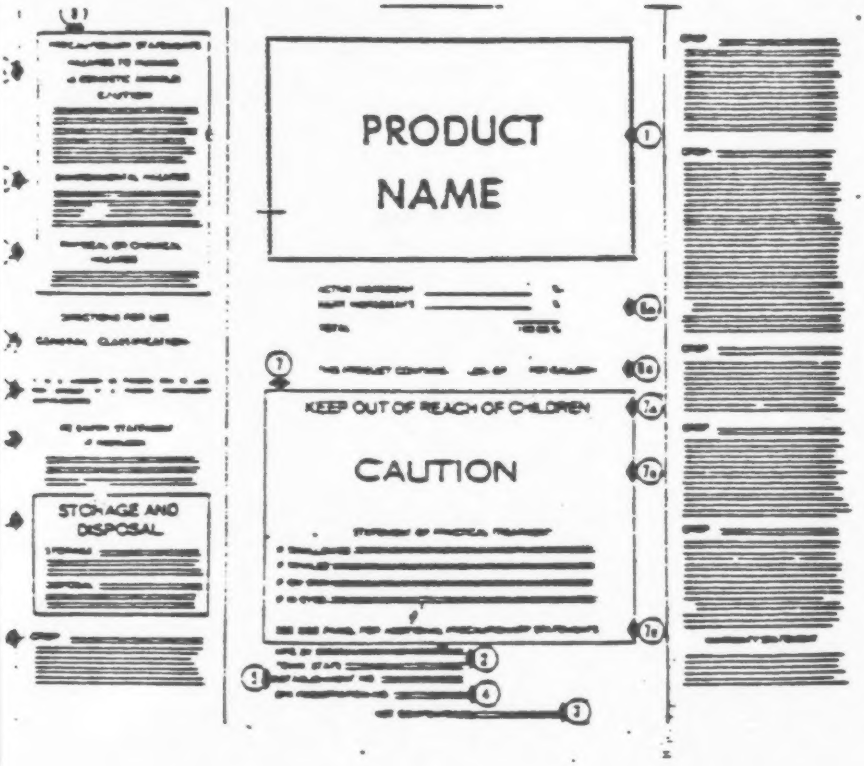
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

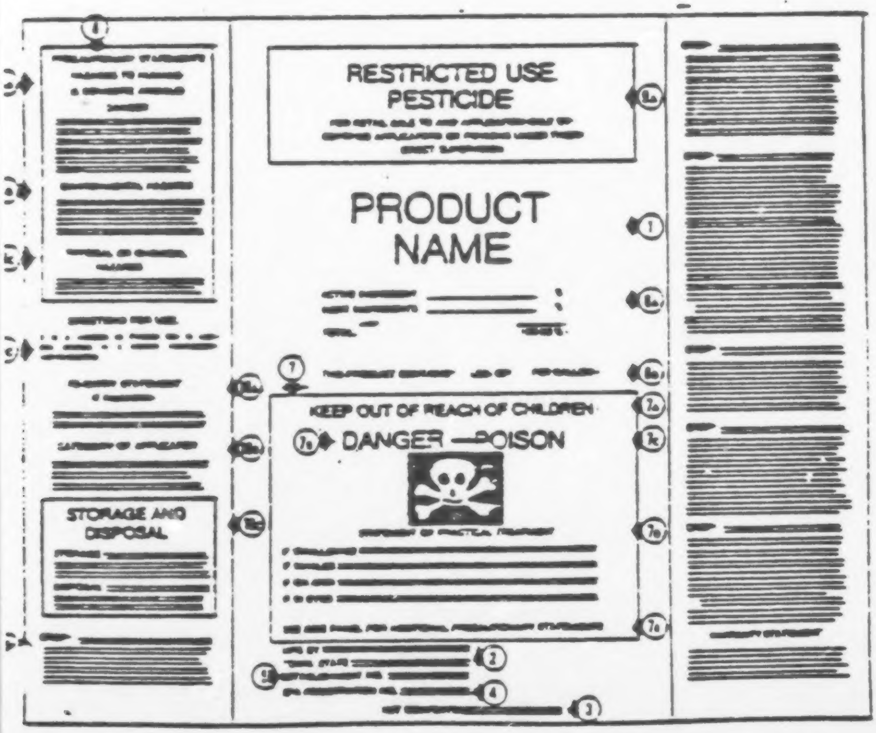
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

APPENDIX IV-2
(continued)

SAMPLE LABELS


PRODUCT
NAME
KEEP OUT OF REACH OF CHILDREN
CAUTION
STORAGE AND
DISPOSAL
1
2
3
4
5
6a
7
7a
7b
7c
8

General Use Pesticide


RESTRICTED USE
PESTICIDE
PRODUCT
NAME
KEEP OUT OF REACH OF CHILDREN
DANGER —POISON
STORAGE AND
DISPOSAL
1
2
3
4
5
7
7a
7b
7c
8

Restricted Use Pesticide

Reproduced from
best available copy.

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	6 point
Above 10 to 15	8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Appendix IV-4
(continued)

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

Appendix IV-4
(continued)

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

Appendix IV-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F"* List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

Appendix IV-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List) Inert Ingredients:

- Acetone
- Acetonitrile
- Acetophenone
- Acrylic acid
- Aniline
- Benzene
- Chlorobenzene
- Chloroform
- Cyclohexane
- Cyclohexanone
- Dichlorodifluoromethane (Freon 12®)
- Diethyl phthalate
- Dimethylamine
- Dimethyl phthalate
- 1,4-Dioxane
- Ethylene oxide
- Formaldehyde
- Formic acid
- Isobutyl alcohol
- Meleic anhydride
- Methyl alcohol (methanol)
- Methyl ethyl ketone
- Methyl methacrylate
- Naphthalene
- Saccharin and salts
- Thiourea
- Toluene
- 1,1,1-Trichloroethane
- 1,1,2-Trichloroethane
- Trichlorofluoromethane (Freon 11®)
- Vinyl chloride
- Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

JUL 2 1984

Subject: Initiation of Reregistration Process for Manufacturing-Use Products and Formulation-Use Products Containing Thiram as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject active ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development, and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this manufacturing-use standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.
2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which are considered part of the data base supporting the registration standard is included.
3. Sets out time-frames for submission of required data.
4. Explains how to revise labeling for manufacturing-use products. (As the Guidance Document explains, labeling is not required at this time.)
5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA has appealled this decision to the U.S. Supreme Court. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any question concerning this Guidance Document, you may contact the Product Manager listed below:

Henry M. Jacoby
Product Manager (21)
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

Phone: (703) 557-1900

Sincerely,

James W.

for Douglas D. Campt, Director
Registration Division

Enclosure

ATTACHMENT A

PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

Name of Products	EPA Registration Number
Dupont Thiram Technical	352-114
Thiram Technical	1117-131
Vancide TM	1965-43
Thiram 75	2749-10
Thiram 100 Fungicide	2749-11
Thiram 65	2749-12
Thiram 80% Wettable Powder	2749-79
Thiram Technical	4581-258
Thiram Technical Wettable Powder	8236-2
Thiram Technical	45728-1
Tetramethylthiuram Disulfide React-Rite® TMTD	46588-1

---

* * * * * * * *

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT, THIRAM

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufacturing-Use Product (MUP), Technical Product (TP), Wettable Powder (WP), and Formulation-Use Product (FUP).

EPA Reg. No.	Co. Name & Address	Active Ingredient	Formulation Type
352-114	E.I. du Pont de Nemours and Company Legal Department D7045 Wilmington, DE 19898	Thiram 99%	MUP and TP
1117-131	Virginia Chemicals Inc. 3340 West Norfolk Road Portsmouth, VA 23703	Thiram 98.5%	MUP and TP
1965-43	R. T. Vanderbilt Company, Inc. 230 Park Avenue New York, NY 10017	Thiram 97.0%	MUP and TP
2749-10	Aceto Chemical Company, Inc. 126-02 Northern Boulevard Flushing, NY 11368	Thiram 75.0%	FUP and WP
2749-11	Aceto Chemical Company, Inc. 126-02 Northern Boulevard Flushing, NY 11368	Thiram 99.45%	MUP and TP
2749-12	Aceto Chemical Company, Inc. 126-02 Northern Boulevard Flushing, NY 11368	Thiram 65.0%	FUP and WP

2749-79	Aceto Chemical Company, Inc. Agricultural Chemicals Division 126-02 Northern Boulevard Flushing, NY 11368	Thiram	75.0%	FUP and WP
4581-258	Pennwalt Corporation Pennwalt Building Three Parkway Philadelphia, PA 19102		99.0%	MUP and TP
8236-2	Prochemie International, Inc. 488 Madison Avenue New York, NY 10022		97.0%	MUP and TP
45728-1	UCB Chemicals Corp. 3340 West Norfolk Road Portsmouth, VA 23703		98.5%	MUP and TP
46588-1	Reactor Products, Inc. P. O. Box 128 Old Summerville Road Armuchee, GA 30105		98.0%	MUP

* * * * * * * *

CHEMICAL INFORMATION FACT SHEET FOR THIRAM, BIS-(DIMETHYLTHIOCARBAMOYL) DISULFIDE

FACT SHEET NUMBER: EPA Case Number 22, Reregistration Standard - THIRAM

DATE ISSUED: June 1, 1984

1. Description of Chemical

Generic Name: Bis-(dimethylthiocarbamyl) disulfide

Common Name: Thiram

Trade Names: Trade names and other names for thiram are AAtak, Arasan, Delsan, Mercuram, Nomersan, Polyram-Alltra, Pomarsol, Spatrete, Tersan, Thimer, Thiramad, Thirasan, Thiuramin, Trametan, Triampa, Tripomol, Tuads, Vancide, Tetramethylthiuram disulfide, TM-95, TMTD, and TMTDS.

EPA Shaughnessy Code: 079801-7
Chemical Abstract Service (CAS) Number: 137-26-8
Year of Intitial Registration: August 5, 1948, DuPont's Tetramethyl Thiuramdisulfide, EPA Reg. No. 352-114
Pesticide Type: Fungicide and Rodenticide
Chemical Family: Organo-sulfur
U.S. and Foreign Producers:

1. E.I. du Pont de Nemours and Company
2. UCB Societe Anonyme, Belgium, for Virginia Chemical Inc., Prochimie International, Inc., and UCB Chemical Corp.
3. R.T. Vanderbilt Company, Inc.
4. Aagrunol Chemicals, B.V., for Aceto Chemical Co., Inc.

2. Use Patterns and Formulations

Application Sites: Fruit, vegetable and ornamental plants (including turf grasses), vegetable and field crop seeds, bananas, propagules of sweet potatoes, tree seedlings, bulbs and cuttings of ornamental bulbs, soil, textiles, polyurethane, wood pulp; and sites around homes, airports, seedling nurseries.

Types of Formulations: Dusts, Wettable Powders and Flowable Suspensions.

Types and Methods of Application: Dusting, Spraying and Dipping.

Application Rates: See Use Patterns in EPA Compendium of Registered Pesticides, Vol. II, Fungicides and Nematicides, Part I, Pages T-30-00-01 through T-30-00-09.

Usual Carriers: Marl, Talc, Clays, Petroleum Oil, Graphite, Vermiculite, Mineral Oil, Charcoal and Water.

3. Scientific Findings

Chemical Characteristics:

Physical State:	Powder (Micromilled)
Color:	Cream to White
Odor:	
Boiling Point:	Not Applicable
Melting Point:	Range 155-156°C
Flash Point:	> 300° F

Toxicity Characteristics:

All toxicological data reviewed by the Agency were found to be lacking in information for evaluation, such as identification of compound tested, dose response information, individual animal information, pathology reports, etc.

Physiological and Biochemical Behavioral Characteristics:

Foliar Absorption: The available data do not provide direct evidence that thiram is or is not absorbed by roots or aerial portions of plants.

Translocation: There is inadequate data to conclude that thiram is translocated in plant tissue, but indirect evidence exists to indicate thiram or a degradate of thiram may enter plant tissue.

Mechanism of Pesticidal Action: Not understood as a fungicide. As a repellant to rodents.

Metabolism and Persistence in Plants and Animals: The metabolism of thiram in plants and animals is not adequately understood.

Environmental Characteristics:

Adsorption and Leaching in Basic Soil Types: Inadequate data.

Microbial Breakdown: Inadequate data.

Loss from Photodecomposition and/or Volatilization: No data.

Bioaccumulation: No data.

Resultant Average Persistence: No data.

Ecological Characteristics:

Hazards to fish and wildlife

Rainbow trout	96-hr LC_{50} = 0.130
Bluegill sunfish	96-hr LC_{50} = 0.044

(Characterized as "very highly toxic" to both cold water and warm water fish.)

Thiram is "moderately toxic" to birds. There is insufficient information to fully characterize the toxicity of thiram to mammals. Generally, the subcutaneous toxicity is "high," the acute oral toxicity is slight to "moderate," and in some species (mouse) "practically non-toxic." Thiram is characterized as "relatively non-toxic" to honeybees and predaceous ladybird beetles.

Potential problems Related to Endangered Species:

Additional data (estimated environmental concentrations, persistence, avian reproduction studies, accumulation) are required to complete the endangered species assessment for thiram.

Efficacy Review Results:

No efficacy reviews were made.

Tolerance Assessments:

1. List of Crops and Tolerances:

The following table lists the present status for tolerances in parts per million for residues of thiram:

Raw Agricultural Commodity	U.S.	Canada	Mexico	Codex
Apples	7	0.1	7	3[b]
Bananas	7[a]	1.0	-	1[c]
Celery	7	-	7	5[b]
Onions (dry bulb)	0.5	-	0.5	-
Peaches	7	7	7	3[b]
Strawberries	7	7	7	3[b]
Tomatoes	7	7	7	3[b]

a. 7 parts per million in or on bananas (from preharvest and postharvest application) of which not more than 1 part per million shall be in the pulp after peel is removed and discarded.

b. A temporary Codex MRL for the residues of dithiocarbamates (of which thiram is a member) expressed n terms of mg CS_2/kg, has been established.

c. Temporary Codex MRLs of 1 and 0.1 ppm have been established for total dithiocarbamates residues (including thiram expressed as ppm CS_2) in or on whole bananas and banana pulp, respectively.

2. Seed Applications:

No tolerances have been established for thiram residues in or on any crop for which thiram is registered solely for seed treatment, because heretofore seed treatment uses have been considered to be nonfood uses. These crops include: barley, beans (dry and succulent), lima beans, beets, broccoli, brussels sprouts, cabbage, cantaloupe, carrots, castor bean, cauliflower, collards, corn (sweet and field), cotton, cowpeas, cucumber, eggplant, endive, flax, forage-fodder grasses, kale, kohlrabi, lentils, lettuce, millet, muskmelons, mustard, oats, okra, onion, peanuts, peppers, pumpkins, radish, rice, rye, safflower, sesame, small-seeded legumes, sorghum, soybeans, spinach, sugar beets, sunflower, swiss chard, tomato, turnips, watermelon, and wheat.

Results of Tolerance Assessment:

Insufficient data are available to assess the adequacy of the tolerance for thiram in or on all thiram-treated commodities having such tolerances: apples, bananas, celery, onions (dry bulb), peaches, strawberries, and tomatoes (40 CFR 180.132). Note that either green onions must be deleted from thiram labels or residue data and a tolerance proposal must be submitted. Also note that the in-furrow treatment for cotton must either be removed from thiram labels or residue data and tolerance proposals must be submitted for forage, seed, and processed products. In addition, many seed treatment uses are registered for thiram on crops not having tolerances for thiram; the continued "nonfood" classification of these uses is contingent upon the receipt of plant metabolism studies demonstrating that thiram residues of concern are not translocated into food/feed crops grown from thiram-treated seed. If residues of concern are translocated, then residue data and tolerance proposals must be submitted for all of these crops (or at least all of the representative commodity members of each involved crop group). Finally, tolerances for thiram animal products have not been established; if the requested animal metabolism studies reveal that thiram residues of concern are transferred to animals, then animal residue data (feeding studies) and appropriate tolerance proposals will be required for ruminants and poultry. It is imperative that the metabolism of thiram in plants and animals be elucidated, since many of the above-noted data gaps are dependent upon the outcome of the metabolism studies. Refer to the appropriate preceding sections for details of data gaps. The data are insufficient to allow the establishment of any crop group tolerances.

No ADI has been established for thiram. The TMRC is 0.7380 mg/day based on a 1.5 kg diet and the relevant tolerances (40 CFR 180.132) and food factors.

Problems that are Known to Have Occurred with Use of the Chemical.

Two workers exposure effects have been identified:

1. Illness in pine seedling planters and handlers resulting from handling thiram-treated pine seedlings without protective clothing (the illness resulted from the ingestion of alcohol after such an exposure).

   Note: Thiram is the methyl analog of Antabuse, bis-(diethylthiocarbomyl sulfide), a drug used in rehabilitating alcoholics.

2. Skin rashes of the hands and head resulting from exposure to thiram in handling thiram-treated pine seedlings.

These health effects have been reduced by restrictions that require workers to wear gloves and protective clothing when handling thiram products.

4. Summary of Regulatory Position and Rationale

Based on historical use experience (human health effects reports) and the benefits from the pesticidal uses, the Agency has determined to allow the registration of thiram products to continue for existing use-patterns until the hazards are better defined by the data requirements under the Thiram Registration Standard.

5. Summary of Major Data Gaps

- All toxicology data, both acute and chronic studies.
- Product chemistry data
- Residue chemistry studies
- Environmental fate
  - Hydrolysis studies
  - Photodegradation studies
  - Metabolism studies
  - Mobility studies
  - Dissipation studies
  - Accumulation studies
- Re-entry
  - Foliar dissipation studies
  - Soil dissipation studies
  - Dermal exposure studies
  - Inhalation exposure studies
- Avian reproduction studies
- Field studies with mammals and birds
- Aquatic organism studies
- Non-target insect studies

6. Contact Person

Eugene M. Wilson
EPA
Office of Pesticide Programs
Registration Division (TS-767-C)
Crystal Mall #2
1921 Jefferson Davis Hwy.
Arlington, VA 22202
Telephone (703) 557-1900

DISCLAIMER: The information presented in this Chemical Information Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.